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EXAMINER				
MOORE, SUSANNA				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,956

Applicant(s)

HENDRIX ET AL

Examiner

SUSANNA MOORE

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments, see Remarks, filed 9/29/2008, with respect to Office Action mailed 4/2/2008 have been fully considered. Some of the rejections have been withdrawn, others have been maintained, and some are new rejections or are new as a result of Applicant's amendments. Thus, this is a Final Office Action. In summary, claims 1-5 and 8 are currently pending and under consideration.

Specification

The objection of the title of the invention is **withdrawn** based on the amendments.

Claim Objections

The objection of claims 6, 9-11 and 14, drawn to an invention nonelected is **withdrawn** based on the amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-5 and 8 under 35 U.S.C. 112, second paragraph, as being indefinite for "heterocyclic" is **withdrawn** based on the remarks.

The rejection of claim 1 for the variable R⁴ is **withdrawn** based on the amendments.

The rejection of claim 8 for the term "medicament" is **withdrawn** based on the amendments.

This is not a new rejection.

Claims 1-5 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound of claim 1 or pharmaceutically acceptable salts of said compound does not reasonably provide enablement for a solvate of a compound of claim 1. The specification does not provide sufficient guidance nor does it enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention is a compound of claim 1, or a pharmaceutically acceptable salt of said compound. There is a **general** teaching of solvates of compound of claim 1 in the specification on page 6, lines 12-15.

The state of the prior art and predictability or lack thereof in the art

It is the state of the prior art that the term "solvate" found in the claims is defined as a compound formed by solvation (the combination of solvent molecules with molecules or ions of the solute. It has been estimated that approximately one-third of the pharmaceutically active substances are capable of forming crystalline hydrates. Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates and hence generalizations cannot be made for a series of related compound (See Vippagunta, et al.)

The scope of "solvate" is not adequately enabled or defined. Applicants provide no guidance as how the compounds are made more active in vivo. Solvates can not be predicted and therefore are not capable of being claimed if the applicant cannot properly enable a particular solvate.

The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance present in the specification or working examples present in the specification are that defines or relates to what solvates are being included in the elected invention.

The breadth of the claims

The breadth of the claims is a compound of claim 1 or a pharmaceutically acceptable salt or solvate thereof.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with various solvents without any direction as to what compounds form solvates with which solvents.

The level of skill in the art is high without showing or guidance as to how to make solvates of a conjugate of claim 1 it would require undue experimentation to figure out the solvents, temperatures and reaction times that would provide solvates of the above compounds.

To overcome this rejection, Applicant should submit an amendment deleting the term "solvates" or provide evidentiary support for solvates.

Applicant traverses the above rejection by stating, "An application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph 35 U.S.C. § 112, unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). *Fiers v. Revel*, 984 F.2d 1164, 24 USPQ2d 1601 (Fed. Cir. 1993). The inventors in the instant disclosure have described how to make and use the invention in terms which correspond in scope to those in the claims. Applicants respectfully submit the Office action fails to provide sufficient evidence or objective reasoning to raise doubt about the truth or accuracy of the inventors' statements on this point. The burden of proof rests on the Patent and Trademark Office to show non-enablement and the evidence of record, as discussed above, fails to meet the burden of proof."

The disclosure provides a general teaching of solvates, which does not support the claimed genus of formula (I) in claim 1. Thus the rejection is **maintained**.

Claim Rejections - 35 USC § 103

The rejection of claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyashita et. al. (Heterocycles, 1990, 31(7), 1309-14) is **withdrawn** based on the remarks.

The rejection of claims 1-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et. al. (CH 396924) is **withdrawn** based on the remarks.

The obviousness found in the following references is also being withdrawn:

CH 396923, Schmidt et. al., 01-1966;

CH 396927, Schmidt et. al., 01-1966;

GB 973361, Ciba; 10-1964;

DE 1156415, Schmidt et. al., 10-1963;

DE 1153023, Schmidt et. al., 08-1963;

DE 1149013, Schmidt et. al., 05-1963.

Double Patenting

No obviousness-type double patenting rejections over co-pending application 10525115 is being made because there is no incidental overlap when R¹ equals a phenyl. Thus, the obviousness-type double patenting was considered but not applied.

No obviousness-type double patenting rejections over co-pending application 10525119 is being made because the copending Application is drawn to method claims and a restriction between compounds and methods was done in the instant Application. Thus, the obviousness-type double patenting was considered but not applied.

No obviousness-type double patenting rejections over co-pending applications 10556437 and 10556224 are being made because there is no incidental overlap when R² equals a phenyl or heteroaryl. Thus, the obviousness-type double patenting was considered but not applied.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624